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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,547	05/10/2001	David A. Sirbasku	1944-00800	6474

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/852,547	SIRBASKU, DAVID A.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 95 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 95 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim 95 has been amended and is under consideration.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 95 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. claim 95 recites "susceptibility of the human to development of estrogen hormone responsive cancer" but then recites "steroid hormone responsive cancer cell" and "inhibition-reversing amount of the steroid hormone". It is unclear if the scope of the cancer cells includes all steroid hormone responsive cancer cell, including those which are progesterone, testosterone and androgen responsive, because the first section of the claim specifies increased susceptibility to estrogen responsive cancers.

Claim 95 twice recites secreted dimeric/polymeric IgA, polymeric IgM and IgG1. It is unclear if the claim is referring to the species of immunoglobulins in the alternative or in a collective group

The rejection of claim 95 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn in light of re-evaluation of the claim in light of the prior art. The abstract of Ohwada et al (Nippon Sanka Fujinka Gakkai Zasshi, 1986, vol. 38, pp. 1707-1712) teaches that in endometrial tissues, IgA is decreased in women over 60 and in cancerous tissues. The abstract does not correlate low levels of IgA with increased susceptibility of developing estrogen responsive cancer. The abstract of Cassamassima et al (Minerva Ginecol, 1997, Vol. 1-2, pp. 7-12) teaches that sIgA concentration was inversely related to CIN grade. One of skill in the art would conclude that the higher grade, having the lower concentration of sIg, would have the highest risk for development into a malignancy. The abstract does not correlate the concentration of sIgA with the development of estrogen responsive malignancy. The abstract of Barton et al (Gut, 1990, Vol. 31, pp. 378-382) teaches that smoking lowers mucosal immunity as evidenced by lowered salivary IgA. the abstract further teaches that

smoking increases the risk of developing squamous tumors of the head, neck and esophagus, but fails to correlate lowered level of salivary IgA with the risk of developing estrogen responsive cancer. Pinegin (U.S. 5,877,147) teaches the administration of drugs to precancerous lesions in epithelial and mucosal tissues, wherein said drugs are thought to act by stimulating mucosal immunity (abstract and column 16, lines 45-60). Pinegin fails to correlate lowered pre-treatment levels of mucosal immunity with the risk of developing estrogen responsive cancers. Kimberly (WO 00/05403) teaches the correlation between the ability of a cell to bind IgA and cellular susceptibility to disease (page 8, line 22 to page 9, line 12). Kimberly teaches the importance of IgA in mucosal immunity and the ability of the inventive method to identify patients at high risk and as a surveillance method for monitoring protective and non-protective antibody levels in response to cancer therapies. (page 11, line 13 to page 12, line 2). Kimberly does not teach quantitation of IgA levels in non-treated individuals as a means of determining the risk of developing and estrogen responsive cancer.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 95 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant method claim requires that the secreted dimeric/polymeric IgA, polymeric IgM and IgG1 is active for inhibiting proliferation of a steroid hormone responsive cancer cell maintained in a suitable nutrient medium under cell growth promoting conditions, and in the absence of an inhibition-reversing amount of the steroid hormone. Growing the steroid hormone responsive cancer in vitro under growth promoting conditions, necessitates the addition of the steroid hormone in some range of concentration. One of skill in the art would reasonable infer that the concentrations of steroid hormone would influence the rate of cell growth, i.e. lower concentration providing for a lower

level of growth and higher concentration providing for a higher level of growth. The claim further requires the absence of an "inhibition reversing amount of the steroid hormone". With the same logic, it can be inferred that a higher concentration of steroid hormone provides more "override" of the ability of the secreted dimeric/polymeric IgA, polymeric IgM and IgG1to inhibit the growth of the steroid hormone responsive cancer and a lower concentration of steroid hormone provides less "override" of the ability of the secreted dimeric/polymeric IgA, polymeric IgM and IgG1to inhibit the growth of the steroid hormone responsive cancer. Thus, the claim requires a concentration of steroid hormone which provides for some degree of cell growth, but no reversal of the inhibition of cell growth caused by the secreted dimeric/polymeric IgA, polymeric IgM and IgG1.The specification provides no objective evidence that the growth stimulating levels of steroid hormone can be separated from inhibition-reversing amounts of the steroid hormone even at low levels. The inhibition of cell growth caused by the secreted dimeric/polymeric IgA, polymeric IgM and IgG1 would also be a function of the concentration of said species after mixing with the growth medium. One of skill in the art would be forced into undue experimentation in order to determine if it was possible to have a level of steroid hormone which supported growth but did not reverse the inhibition of secreted dimeric/polymeric IgA, polymeric IgM and IgG1 for every type of steroid responsive cancer cell in combination with every sampled body fluid which would reasonable be expected t vary in concentration of secreted dimeric/polymeric IgA, polymeric IgM and IgG1 and therefore cause a variation in the amount of steroid d hormone which would reverse the inhibition of secreted dimeric/polymeric IgA, polymeric IgM and IgG1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A. Canella/
Ph.D., Primary Examiner, Art Unit 1643